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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,109	07/01/2003	Richard C. Ewers	USGI-004 B	3376
20350	7590	03/15/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			HAND, MELANIE JO	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/612,109

Applicant(s)

EWERS ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 13-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/28/04, 6/17/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of species 1 of group I, claims 1-12 in the reply filed on December 29, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Examiner requests that applicant acknowledge the withdrawal of claims 13-45 in an amendment to the claims or response to this Office action.

Priority

Acknowledgment is made of applicant's claim for priority under copending Provisional Application No. 60/433,065, filed on December 11, 2002.

Information Disclosure Statements

The information disclosure statements (IDS) submitted on October 28, 2004 and June 17, 2005 were filed after the mailing date of the Application on June 1, 2003. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

The references cited by applicants in the IDS and listed on the numerous 1449's have been made of record. While the statements filed clearly do not comply with the guidelines set forth in MPEP 2004 regarding both the number of references cited and the elimination of clearly

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irrelevant art and marginally cumulative information, compliance with these guidelines is not mandatory. Furthermore, 37 CFR 1.97 and 1.98 does not require that the information be material, rather they allow for submission of information regardless of its pertinence to the claimed invention. Also, there is no requirement to explain the materiality of the submitted references, however, the cloaking of a clearly relevant reference by inclusion in a long list of citations may not comply with Applicant's duty of disclosure, see Penn Yan Boats, inc. V. Sea Lark boats Inc., 359 F. Supp. 948, aff'd 479 F. 2d. 1338.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 6-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Martin et al (U.S. Patent Application Publication No. 2003/0167071).

With respect to **Claim 1**: Martin teaches a suture fastener 100 operable in conjunction with delivery catheter 520. Catheter 520 and fastener 100 are part of kit 700 that is also comprised of a needle, which is useable with the catheter 520, and by nature would be capable of being translatably disposed within catheter 520 due to its smaller size, as catheter 520 has to be large enough to accommodate fastener 100.

With respect to **Claims 6,7**: Martin teaches that fastener 100 with coil 102 is disposed on the distal end of loading catheter 200 as is best seen in Fig. 3. ('071, ¶¶ 0055,0057)

With respect to **Claim 8**: Martin does not teach a coil screw but does teach a coil comprised of moldable shape-memory material. Since a coil screw is also a coil shape that would also provide the function of holding suture strands in place, it would be obvious to one of ordinary skill in the art to modify the coil taught by Martin by substituting a coil screw, since screws by nature have a sharp tip for penetrating a substrate and frictionally fitting with said substrate.

With respect to **Claim 9**: Martin teaches that coil element 102 is comprised of a plurality of coils. ('071, ¶ 0013)

With respect to **Claim 10**: As can best be seen in any of Figs. 1-6 taught by Martin, the coil element 102 is coaxial with catheter 200.

With respect to **Claim 11**: Martin teaches that coil element 102 is slidable to a desired position along catheter 200. ('071, ¶¶ 0056,0057)

With respect to **Claim 12**: Martin teaches that delivery catheter 520 comprises a push rod 522. ('071, ¶ 0071)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of Kim (U.S. Patent No. 5,676,670).

With respect to **Claim 2**: Martin teaches that fastener 100 is comprised of two or more interlockable elements 300 and cites that the element 300 is a braid, but does not teach that the braid is comprised of stainless steel. Kim teaches a catheter for bypass procedure and teaches that supplying an additional layer of braided stainless steel material to a lumen catheter is conventional practice ('670, Col. 10, lines 37-39), therefore it would be obvious to one of ordinary skill in the art to modify the delivery catheter 520 or the braid taught by Martin to be comprised of stainless steel.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al ('071) in view of O'Keefe (U.S. Patent No. 6,921,378).

With respect to **Claim 3-5**: Martin teaches apertures 504,508 in the fastener 100, however they are parallel to the longitudinal axis of the fastener and are not sinusoidal. O'Keefe teaches a drainage catheter having slots present only at a distal end of a catheter, therefore increasing in density as the length from the distal end decreases, and that these slots are of a curved shape, which Examiner asserts encompasses a teaching of sinusoidal slots. O'Keefe teaches that these slots are used to aid liquid flow through the retention end of the catheter. ('378, Col. 11, lines 4-11) Therefore placing slots in delivery catheter 520 at a distal end would be obvious to one of ordinary skill in the art as the catheter 520 performs a substantially identical function to that taught by O'Keefe.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written over the printed name and title.